

REMARKS

Claim Amendments

Claims 1-3, 5-7, 11-19, 21 and 22 are pending in this application. Claims 15-17 have been canceled without prejudice.

Independent claims 1, 18 and 22 have been amended to improve form and to specify that the light output intensity of the luminescent device is pre-determinable by calculating the half-life correction of the GTLS. Support for these amendments is found, for example, on page 3, lines 14-26 of the specification.

Claims 1 and 18 have also been amended to include the feature that the luminescent device is shaped (Fig. 5 and 8) and sized to removably fit (page 7, line 12) in an individual well of a standard size well plate. No new matter or issues are presented by these amendments.

Claim Objections: Typographical Errors

The Examiner has pointed out that claims 1 and 19 contain informalities. In response to this objection, the word 'plat' has been replaced with the word 'plate' in claim 1, and the word 'comprises' has been reinserted into claim 19.

Claim Rejections: 35 U.S.C. § 112

1. 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 16, 17, 21 and 22 on the basis that the claims contain subject matter that was not described in the specification as filed. Claims 16 and 17 have been canceled without prejudice to prosecuting these claims in a continuing application. Applicant

respectfully requests reconsideration of the rejections of claims 21 and 22.

The Examiner asserts that the specification does not support the standard size well plate being a 6, 12, 24, 36, 48, 96, 384 or 1536 well plate, as recited in claim 21. Applicant respectfully disagrees. The person skilled in the art is well aware of the kinds of plates that can be used within the light measuring apparatus described. Standard size well plates are very commonly used and it is quite clear from the description that the inventor intended the luminescent device to have universal applicability to all such standard size well plates. The Examiner is referred, for example, to page 1, in which the invention is described as being useful to 'calibrate...scientific apparatus measuring optical output' (lines 5-7). This is a very broad applicability, which is further elaborated on page 5, lines 8-11, in which it is stated that the luminescent device is shaped and sized to be suitable for insertion into an individual well of a standard size well plate - the examples given of a 96, 384, or 1536 well plate are simply non-limiting examples. On the basis of these arguments, it is submitted that the amended claim 21 is supported by the description as filed.

The Examiner did not identify any elements of claim 22 that were not supported by the specification. Applicant respectfully submits that all elements are disclosed in the specification. See, e.g., page 9, line 29 – page 11, line 9 and page 5, lines 8-18.

2. 35 U.S.C. § 112, second paragraph

Claims 16, 17 and 22 stand rejected as being indefinite. Applicant respectfully requests reconsideration of this rejection. The rejection of claims 16 and 17 is moot in view of Applicant's cancellation of these claims without prejudice to prosecuting them in a continuing

application. Similar to the rejection under § 112, first paragraph, the Examiner did not identify any elements of claim 22 that were indefinite. For the reasons set forth above, Applicant submits that claim 22 is definite.

35 USC § 103(a); Obviousness

The Examiner has rejected claims 1, 3 and 21 as being unpatentable over Kessler in view of Nast. Applicant respectfully requests reconsideration of this rejection.

Claim 1 recites an outer casing that is shaped and sized to fit within an individual well of a standard size well plate. The Oxford English Dictionary defines the term 'to fit' as '*possessing the right measurements or size; fitting exactly; adjusted to the contours of a receptacle*'. Kessler does not disclose a device that is adjusted to the contours of a receptacle. It is submitted, as discussed above, that the structural limitations would be quite clear to the person skilled in the art, because the common general knowledge teaches the shape and size of the individual wells that would be present in a standard size well plate for use in any particular light measuring apparatus. No further structural limitations are required. Therefore, it is submitted that the invention is patentable over Kessler.

Nast does not cure the deficiencies of the Kessler disclosure. Nast discloses a magnetic and mechanical pick-up tool. Although it may suggest the use of magnetic portions so that objects may be picked up, it does not disclose or suggest a device of amended claim 1 in which the magnetic outer casing of the device is shaped and sized to removably fit in an individual well of a standard size well plate. Therefore, it is submitted that claim 1 is patentable over Nast.

There are some significant advantages to a device that is shaped and sized to 'fit' within a well, rather than a device which can simply be placed within a well but does not conform to its shape. For example, the device of amended claim 1 will not move about within the well, as a long device of the shape of the device of Kessler might. If a light standard device moves about, it could affect the accuracy of the reading of light output. The device of claim 1 therefore has the advantage that it can be used to ensure that the optical instrument is taking an accurate reading of light output at the same time as reading samples. Furthermore, the device is removable, which avoids the waste and expense of manufacturing and purchasing sample holders such as standard size plates etc. that contain sealed-in light standards. Finally, Kessler restricts any discussion of size and shape to one that would only be placed within a 6-well plate, and does not disclose a device that can be fitted into a sample holder of any other standard size well plate, such as a PCR plate, conical well plate, or 6, 12, 24, 36, 48, 96, 384 or 1536 well plate. This structural limitation ensures that the invention can be put to work in any optical instrument that uses a standard size well plate.

It is submitted that on the basis of these and arguments, amended claim 1 and dependent claims 3 and 21 are novel and inventive over the disclosure of Kessler in view of Nast.

The Examiner has rejected claim 2 as being unpatentable over Kessler in view of Nast and MacHutchin. Applicant respectfully requests reconsideration of this rejection. Claim 2 depends from claim 1 and is believed patentable over Kessler in view of Nast for the reasons set forth above. MacHutchin is cited only for teaching that the number of curies of gas depends on the gas pressure, and does not disclose, teach or suggest the removable fit configuration of the

lumination device in claim 1. Therefore, claim 2 is patentable over the cited references.

The Examiner has rejected claims 5, 7, and 12 as being unpatentable over Kessler in view of Nast and Adams. Applicant respectfully requests reconsideration of this rejection.

Claims 5, 7 and 12 depend from claim 1 and are believed to be patentable over Kessler in view of Nast for the reasons set forth above. Adams is cited only for providing a plurality of neutral density filters and does not overcome the deficiencies of Kessler or Nast with regard to claim 1. Therefore, claims 5, 7 and 12 are patentable over the cited references.

The Examiner has rejected claim 6 as being unpatentable over Kessler in view of Nast, Adams and Terashita. Applicant respectfully requests reconsideration of this rejection. Claim 6 depends from claim 1 and is believed to be patentable over Kessler in view of Nast for the reasons set forth above. The Examiner cites Adams only for teaching neutral density filters and Terashita only for disclosing that a neutral density filter comprises a glass or plastic plate. However, neither Adams nor Terashita disclose, teach or suggest the removable fit configuration of the lumination device in claim 1. Therefore, claim 6 is patentable over the cited references.

The Examiner has rejected claim 11 as being unpatentable over Kessler in view of Nast and Gelman. Applicant respectfully requests reconsideration of this rejection. Claim 11 depends from claim 1 and is believed to be patentable over Kessler in view of Nast for the reasons set forth above. The Examiner cites Gelman only for disclosing a scalebar graticule. Gelman does not, however, disclose, teach or suggest the lumination device recited in claim 1.

Therefore, claim 1 is patentable over the cited references.

The Examiner has rejected claims 13-15 as being unpatentable over Kessler in view of Nast and Leveille. Claim 15 has been canceled without prejudice. Applicant respectfully requests reconsideration of the rejection of claims 13 and 14. Claims 13 and 14 depend from claim 1 and are believed to be patentable over Kessler in view of Nast for the reasons set forth above. Leveille is cited only for providing a calibration light kit, and does not overcome the deficiencies of Kessler or Nast with regard to claim 1. Therefore, claims 13 and 14 are patentable over the cited references.

The Examiner has rejected claims 16-19 and 22 as being unpatentable over Kessler in view of Nast and Valenta. Claims 16 and 17 have been canceled without prejudice. Applicant respectfully requests reconsideration of the rejections to claims 18, 19 and 22. Claims 18 and 22, as amended, are directed to a method of analyzing a sample and a method for calibrating a light measuring apparatus, respectively. Both claims recite that a luminescent device is removably fit into a standard size well plate and left in the well plate during use so that the calibration of the light measuring apparatus may be tested whilst measuring the light output of an analyte sample. Claim 18 has been further amended to indicate that the intensity of the luminescent device is pre-determined by calculating the half-life correction (page 3, lines 20-26). Neither Kessler, Nast nor Valenta disclose or suggest these distinguishing features and therefore the subject matter of claims 18, 19 and 22 is patentable over these prior art documents.

The advantages of the methods recited in claims 18, 19 and 22 will now be discussed.

Calibration of such light measuring apparatus is usually complicated and time consuming and requires additional equipment that needs a power source, is bulky and occupies the entire sample space in the light measuring apparatus. It is not therefore possible to check the calibration of the machine whilst measuring test samples, so the results may be less accurate than is desirable (page 2, lines 20-32).

The methods of claims 18 and 22 solve this problem by utilizing a luminescent device that is removably fitted into a standard size well plate and left in the well plate during use. These methods have the advantage that the luminescent device can be used to ensure that the optical instrument is taking an accurate reading, in absolute terms, of light output readings at the same time as reading samples. Furthermore, the device is removable, which avoids the waste and expense of manufacturing and purchasing sample holders such as standard size plates etc that contain sealed-in light standards. Finally, the advantages of using a luminescent device that can fit within a well, rather than be simply placed into a well, are discussed above.

Kessler discloses a device that could be removably inserted into the well of a 6-well plate. However, it restricts any discussion of size and shape to one that would only be placed within a 6-well plate, and does not disclose a device that can be *fitted* into an individual well of any size of standard size well plate. By way of explanation of this point, the Examiner is referred to the Oxford English Dictionary, in which the definition of 'fit' as 'possessing the right measurements or size; fitting exactly; adjusted to the contours of a receptacle'. Kessler does not disclose a device that is adjusted to the contours of a receptacle. Therefore, the invention is novel over Kessler.

The Examiner has expressed the opinion that Valenta teaches those features that are lacking in Kessler. Valenta discloses a method, an apparatus and a standard for normalizing two or more photodetectors relative to each other. The object of the invention of Valenta is to enable a user to ensure that all photomultipliers in a system are normalized, so that a readout of the signal from a sample will be the same, no matter which photomultiplier performs the reading. In other words, the counting efficiencies among the multiple photodetectors can be offset. Applicant acknowledges that Valenta discloses the idea of including a light standard within a well of a sample holder so that a method of calibration may be carried out at the same time as testing samples. However, Valenta does not disclose that the device can removably fit within the wells, or that any absolute calibration should be performed. Therefore, the invention is novel over Valenta.

As stated by the Examiner in his response to arguments, the test of inventive step is what the combined teachings of two documents would have suggested to those of ordinary skill in the art. Applicant suggests that although the person skilled in the art *could* have combined these two documents in order to develop the present invention, he *would not* have. The disclosure of Kessler teaches away from using a light standard at the same time as reading test samples, because it explicitly states that the test is to be carried out prior to testing of samples. Nowhere in the disclosure of Kessler is it suggested that it would be useful to be able to calibrate an optical instrument at the same time as performing analysis of samples. There is simply no prompting to the person skilled in the art to develop the invention.

Valenta does not at any stage suggest that it is necessary or even desirable to perform an absolute calibration step, or that the light standard should removably fit in the well, or that the

resulting advantages as outlined above are desirable. Therefore, again, there is no prompting to the person skilled in the art to develop an apparatus and methods for achieving these advantages. It is submitted that only an ex post facto view of the prior art could lead to an opinion that the present invention is obvious. There is no suggestion, prompting towards or disclosure of the combination of features of the present invention, in Kessler or Valenta, either alone or in combination. For all of the foregoing reasons, Applicant submits that claims 18 and 22 are patentable over the cited prior art documents.

The Examiner has also expressed the opinion that claims 18 and 19 lack an inventive step over Kessler in view of Valenta. Applicant respectfully requests reconsideration of this rejection. Claim 18 is directed to a method of analysing a sample in which the absolute light output can be obtained, by comparison to the reference standard. This is achieved because of the presence of a luminescent device of a predetermined intensity.

As the Examiner notes, Kessler lacks that the luminescent device is placed and left in a well during testing of samples. Valenta does disclose the use of a light standard within a well, but does not disclose a method in which a reading of light output of the apparatus is adjusted to the predetermined light intensity of the luminescent device, as recited in claim 18. Instead, Valenta teaches that different photomultipliers should be normalized with respect to each other. Using the method of Valenta, the user cannot be sure that the results are accurate in absolute, rather than relative terms.

Neither Kessler nor Valenta discloses or suggests the combination of features of the present method, or the corresponding advantages. Therefore, the person skilled in the art would

not, on reading these two documents, be prompted to develop the method. On the basis of these amendments and arguments, it is submitted that the method of claims 18 and 19 is both novel and inventive over the disclosure of Kessler and Valenta, either alone or in combination.

In view of the foregoing, Applicant submits that the Examiner's objections have been overcome and that this application is in condition for allowance. Should any issue remain to be resolved, Applicant requests that the Examiner telephone the undersigned.

Dated: December 2, 2008

Respectfully submitted,

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